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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/465,338	12/17/99	ALBERT K	PT-1817

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EXAMINER	
PULLIAM, A	
ART UNIT	**PAPER NUMBER**
1615	9

DATE MAILED: 10/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/465,338	ALBERT ET AL.	
	Examiner	Art Unit	
	Amy E Pulliam	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *03 August 2000* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-25,27-53,56-60 and 62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *12,14,15,17,18,30,32,33,35-44,46-55,60 and 62* is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☒ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☒ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of the Amendment B, received August 3, 2000.

Claims 1-7, 9-25, 27-53, and 56-62 are pending. Claims 8, 26, 54, 55, and 61 have been withdrawn due to a restriction requirement.

Allowable Subject Matter

Claims 44, 46, 48-53, 60, and 62 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Objections

Claims 12, 14, 15, 17, 18, 30, 32, 33, 35-44, 46-53 and 62 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can not depend on another multiple dependant claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-25, and 27-36 are rejected under 35 U.S.C. 102(b) as being anticipated by EPA 856 313 to Geoghegan *et al.* ('313).

EPA '313 discloses a controlled absorption diltiazem pellet formulation for oral administration to control hypertension and angina comprising a core of diltiazem or a pharmaceutically acceptable salt thereof, and a multilayer membrane surrounding the core and containing both a water insoluble and a water soluble polymer (abstract). EPA '313 further discloses that the formulation is preferred as a once-daily product to be administered before bedtime, and to be released at the following rates:

a. from 0 to 35% after 2 hours

b. from 4 to 45% after 4 hours

c. from 30 to 75% after 8 hours

d. from 60 to 95% after 13 hours

e. not less than 85% after 24 hours.

These release rates overlap those claimed by applicant in the instant application. Further, EPA '313 teaches that the water insoluble polymer can be replaced by a copolymer of acrylic and methacrylic acid esters (p 28, claim 10), and that the water soluble polymer can be HPMC (p 28, claim 7). EPA '313 also teaches that the core may comprise an organic acid, a lubricant (p 5, l 15-29), and other pharmaceutically acceptable components. In addition, throughout the examples, EP '313 teahes varying amounts of active ingredient, including 120, 240, and 90 mg. Further, EPA '313 teaches tablet, pellet, and capsule formulations (exs. 8, 14, 21). Although EPA '313

does not disclose the exact release rates claimed by applicant, the ranges claimed fall within the range disclosed by EPA '313, and therefore are anticipated by the reference.

Applicant's arguments have been fully considered but are not found persuasive. First, applicant argues that the '313 patent does not teach a Cmax and Tmax as claimed by applicant, and specifically points out that examples 14 is based on example 1, which has a Cmax of 5 hours. However, the examiner would like to direct the applicant's attention to page 25, where it states that the Tmax of the '313 formulation is 13.00 hours. Further, '313 teaches that because of this extended Tmax, this formulation is definitely suitable for a once daily formulation. Therefore this rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 9-25, 27-43, 45, 47, and 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over EPA 856 313 to Geoghegan *et al.* ('313) as applied to claims 1-36 above.

EPA '313 does not teach all of the specific amounts of Diltiazem present in the formulation, nor do they teach the specific wetting agent claimed by applicant. However, the formulation disclosed in EPA '313 does teach a varied range of the

amount of active ingredient, as well as the presence of additional additives, such as lubricants. Further, the formulation also releases the drug at the same rate as that claimed by applicant, therefore, it appears that these limitations do not render any unexpected results. It is the position of the examiner that these are limitations which would be routinely determined by one of ordinary skill through minimal experimentation, as being suitable, absent the presentation of some unusual and/ or unexpected results. The results must be based on the specific limitations.

Applicant's arguments have been discussed above, and this rejection is maintained for the reasons stated above.

Claims 1-7, 9-25, 27-43, 45, 47, and 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/00093 to Deboeck *et al.* ('093). WO '093 discloses an extended release galenical form of Diltiazem or a pharmaceutically acceptable salt, with a wetting agent, coated with a microporous membrane comprising at least a water soluble polymer and a pharmaceutically acceptable adjuvant. WO '093 further teaches that the composition comprises beads containing between 120 and 480 mg of the active ingredient, with the wetting agent, and the beads are coated with the microporous membrane (p 19, claim 1). WO '093 further teaches that the water soluble polymer or copolymer can include HPMC and Eudragit (p 8, l 21-28). Further, WO '093 teaches that the following ingredients are included in the formulation: wetting agents such as fatty acid esters of saccharose (2-20%), microcrystalline cellulose (5-25%),

polyvinylpyrrolidone (1-15%), titanium oxide, surfactants such as tween, antifoaming agents, magnesium stearate, and talc (see pages 8-10). These are the ingredients disclosed by applicant as being present in the formulation. WO '093 also teaches that the formulation is for once daily administration. WO '093 does not teach the exact rates of release as claimed by applicant, nor do they discuss the rates of release after 8 hours, nor do they disclose all of the specific amounts of the above mentioned ingredients. However, WO '093 does teach overlapping rates of release to those claimed by applicant, and they do teach the same ingredients as claimed by applicant. It is the position of the examiner that the present application is not patentably distinct from WO '093, as they contain the same ingredients, in the same formulation, with overlapping rates of release, even though WO '093 does not disclose the specific amounts of all the ingredients. It is the position of the examiner that the specific amounts of those ingredients which are not disclosed in WO '093 are limitations which would be routinely determined by one of ordinary skill in the art through minimal experimentation, absent the presentation of some unusual and/ or unexpected results. The results must be those that accrue from the specific limitations. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to create a controlled release formulation of Diltiazem, based on the teachings of WO '093, and experiment with and vary the specific amounts of the ingredients, in order to achieve the desired rate of release.

Applicant argues that WO '093 does not teach the exact Cmax and Tmax as claimed by applicant. The examiner acknowledges this fact, and this is why the WO

'093 reference is used as an obviousness reference, not an anticipation reference. It is the position of the examiner that because WO '093 contains the same ingredients in the same formulation, with overlapping release rates, applicant's invention is not patentably distinct from the prior art, therefore, this rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is (703) 308-4710. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

308-7922 for regular communications and (703) 308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Amy E. Pulliam
Patent Examiner
Art Unit 1615
October 9, 2000

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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